What if physicians could practice complex vascular procedures on models of their patients’ blood vessels before performing them on the actual patients?

A team of vascular surgeons at the Gates Vascular Institute (GVI) is doing just that using 3D-printed vascular flow models. Over the past several years, vascular surgeons at the GVI have used patient-specific 3D-printed vascular models produced by the Jacobs Institute (JI) from patient imaging to plan for complex endovascular abdominal aortic aneurysm (AAA) repair procedures. After having performed procedural simulations on the models, the physicians reported that they were better prepared for potential complications. They also related finding anatomical anomalies that were not apparent in the imaging, which helped them perform the actual case.

What is an abdominal aortic aneurysm (AAA)?

When an area of the wall of a patient’s abdominal aortic artery, the main artery carrying oxygenated blood from the heart to organs in the body, becomes weakened, it can bulge out and create an abdominal aortic aneurysm (Figure 1). When an aneurysm reaches a certain size or when it starts growing rapidly, it may be at risk of rupture, which leads to bleeding and often death. In the United States alone, approximately 10,000 people die per year from aortic aneurysm ruptures.

How are AAAs treated?

Open or endovascular surgery may be performed electively to repair an aneurysm before a rupture can occur. Open surgical repair of aortic aneurysms involves cutting into the patient’s abdomen and replacing a portion of the weak and bulging vessel with a graft made of a synthetic material. In an endovascular repair procedure, called endovascular aortic repair or EVAR, the physician deploys catheters and guidewires, under x-ray guidance, through a puncture in the patient’s leg via the femoral artery to the aortic aneurysm. Once there, the physician advances a collapsed graft through the catheter and expands it against the offending vessel wall causing blood to bypass the aneurysm.

When an abdominal aneurysm is near the renal arteries and the superior mesenteric artery (collectively referred to as the visceral vessels), it is called a Juxtarenal Abdominal Aortic Aneurysm (JAAA). Since use of a regular aortic graft to treat a JAAA may cut off the flow of...
blood to the visceral vessels, fenestrated endovascular aortic repair (FEVAR) was recently developed to avoid this. In a FEVAR case (see Figure 2, courtesy Cook Medical), a patient-specific aortic graft is custom made that has small windows where the patient’s superior mesenteric artery (SMA) and renal arteries branch off from the aorta. Small stents are placed through the graft windows into each visceral artery to retain blood flow.

**How do 3D-printed models help plan for FEVAR procedures?**

Performing FEVAR requires the physician to use a large number of devices at the same time and to become familiar with particular graft orientation techniques. 3D-printed patient-specific models provide the opportunity for additional hands-on training for physicians as an adjunct to traditional training delivered by medical device manufacturers (MDM).

Similarly, hands-on practice on patient-specific 3D-printed models allows physicians to better plan for complex cases as the 2D images traditionally used for planning do not provide all of the anatomical information needed to make treatment decisions. During operations, surgeons often need to respond to unexpected findings on the fly. Performing the procedure on a patient-specific model before actually performing it on the patient can provide the physician with this important information ahead of time. It also allows the surgeon to identify potential complications in a risk-free environment and develop strategies for dealing with the complications should they occur during the actual procedure. 3D-printed models can also be used to test the feasibility of endovascular solutions on patients with complicating factors such as stenosis and vessel tortuosity.

Maciej L. Dryjski, MD, PhD, professor of surgery and vice chair for faculty development at UB’s Jacobs School of Medicine and Biomedical Sciences and medical director of vascular and endovascular surgery for Kaleida Health, was the first vascular surgeon to use patient-specific 3D-printed AAA models to practice for his first FEVAR procedure. He performed the procedure on a 3D-printed model of his patient the day before the actual procedure under fluoroscopy guidance in a clinical training lab. To simulate blood flow, the models were connected to a cardiac pulsatile pump that drew from a water bath heated to body temperature. The clinical setup is shown in Figure 3.

“Carrying out a complex AAA treatment on a patient-specific 3D-printed model before performing it on the actual patient provides me with additional anatomical information that imaging studies do not and allows me to identify potential complications, so I can plan and be ready for them in the case. Finally, it allows me to test the feasibility of an endovascular versus a surgical approach in a patient with arterial stenosis and/or vessel tortuosity.”

-Maciej Dryjski, MD

Two of Dr. Dryjski’s colleagues, G. Richard Curle, MD, FACS, and Linda Harris, MD, also performed their first FEVAR procedures on 3D-printed models of their patients. Their feedback indicated that they felt more confident going in to their first FEVAR cases and were more prepared for potential complications after having performed the procedural simulations on the patient-specific models. They also reported finding anatomical anomalies that were not apparent in the imaging and for which they were now prepared in the actual case. All three cases had excellent patient outcomes.
Celebrating EMS Week

“EMS STRONG is Stronger Together” were the words on a banner hung proudly in the GVI’s emergency room entrance on May 23. The banner celebrated this year’s theme for National Emergency Medical Services (EMS) Week, May 20-26, 2018, as events were held at Kaleida Health’s emergency departments throughout Western New York, including Erie County Medical Center (ECMC). National EMS Week unites local communities and medical personnel to publicize safety and honor the dedication of those who provide the day-to-day lifesaving services of medicine’s “front line.”

The GVI hosted a cookout in the ambulance bay, with easy access for emergency medical service workers. Sodexo grilled up burgers and hotdogs, accompanied by cookies, ice cream, and soda for EMTs working the day shift. For those burning the midnight oil, they were offered boxes lunches with chips, cookies, and soda.

“Kaleida Health is pleased to honor the emergency medical service workers who go into our communities every day to work with patients and families to provide quality care before they arrive at the hospital. EMS Week is a great opportunity for us to express our appreciation for all they do for our patients.” said Dr. David Janicke, medical director, emergency department and neuroscience emergency department at the Buffalo General Medical Center/GVI.

‘Every Minute Saves Brain’ Event

Buffalo General Medical Center/Gates Vascular Institute (BGMC/GVI) sponsored an educational program in June for Emergency Medical Service (EMS) providers, called “Every Minutes Saves (EMS) Brain.” This educational panel featured David Janicke, MD, medical director emergency department and neuroscience emergency department at BGMC; Ken Snyder, MD, PhD, vice president of physician quality at Kaleida Health; and Robert Sawyer, MD, co-medical director of BGMC/GVI comprehensive stroke program. The respected panelists covered a variety of topics, including challenges in stroke recognition, collaborative EMS and stroke center initiatives, 2018 Guidelines for Acute Ischemic Stroke, inter-facility transfers, advances in comprehensive stroke care, case presentations, and an acute thrombectomy demonstration.

“EMS providers are critical members of the stroke team at the GVI and it is of utmost importance to keep them abreast of changes in stroke treatment. We are pleased that so many of them came out on a week night to learn more about stroke and the role they play in its accurate identification,” stated Dr. Sawyer.

Sonya Noor, MD, FACS

Sonya S. Noor, MD, FACS is an established vascular surgeon who started an independent practice called Buffalo Endovascular and Vascular Surgical Associates (BEVSA) in 2007. She now has two practice locations, one in Buffalo and one in Williamsville.

Dr. Noor has over 13 years of experience in her field. Her career in medicine began when she graduated from Calcutta Medical College in Calcutta, India in 1992. After moving to the United States, she completed a residency at the State University of New York Upstate Medical University in Syracuse, followed by her fellowship at the University at Buffalo and Arizona Heart Hospital. Dr. Noor remains a distinguished member of the American Medical Association, the Western New York Vascular Society, and the Eastern Vascular Society. She is the also the current president of the American College of Surgeons’ local chapter (ACS) and a member of the Society for Vascular Surgery (SVS).

Dr. Noor is dual board certified by the American Board of Surgery and is regarded as a leading vascular surgeon, as well as being a specialist in peripheral and endovascular surgery. Expert procedures undertaken by her include abdominal aortic aneurysm endovascular and open repair, carotid surgery and stenting, peripheral vascular disease balloon, stenting and atherectomy, and bypass procedures and all venous procedures.

She stays current on the latest procedures by serving as faculty on multiple national conferences such as new cardiovascular horizons, Chicago Vascular Horizons, Chicago Vascular Conference, and Amputation Prevention Conference, Gates Vascular Symposium, Failure Analysis Advisory Counsel, to name a few. Presently, Dr. Noor continues to provide exceptional care and support to the patients in our community. She also serves as medical director of endovascular services at Buffalo General Medical Center and Gates Vascular Institute, as well as medical director of vascular service at Olean General Hospital. Dr. Noor is affiliated with DeGraff Medical Center and Access Care of Williamsville, NY.

Dr. Sonya Noor was recently awarded Top Vascular Surgeon in 2017 and 2018 and most recently awarded Women of Distinction 2018.
Findings from two recent clinical trials confirm what the GVI stroke team has observed for many years – the rate of tissue death among patients following stroke differs greatly and, using advanced imaging, it is possible to identify stroke patients who have salvageable brain tissue even when they are beyond the accepted treatment window of six hours. While there is no question that time is brain and that the odds of better patient outcomes increase when the patient is transported to the hospital as soon as possible, these findings provide hope that certain acute ischemic stroke (AIS) patients are still candidates for endovascular stroke intervention even up to 24 hours after their symptoms began.

The two clinical trials, DWI or CTP Assessment with Clinical Mismatch in the Triage of Wake-up and Late Presenting Strokes Undergoing Neurointervention with Trevo (DAWN) and Endovascular Therapy Following Imaging Evaluation for Ischemic Stroke Trial (DEFUSE 3) are changing the diagnostic imaging used on patients with suspected acute ischemic stroke and lengthening the endovascular treatment window for certain stroke patients with large vessel occlusions (LVOs) in their brains. These changes are reflected in the 2018 Guidelines for the Early Management of Patients with Acute Ischemic Stroke that include significant changes from the 2013 AHA/ASA Guidelines for the Early Management of Patients with Acute Ischemic Stroke and the 2015 AHA/ASA Focused Update of the 2013 Guidelines for the Early Management of Patients with Acute Ischemic Stroke Regarding Endovascular Treatment.

The multi-center DAWN trial randomly assigned patients with LVOs — whose stroke symptoms had begun 6 to 24 hours earlier and whose MRI or Perfusion CT imaging indicated a mismatch between the severity of the clinical deficit and the infarct volume — to either thrombectomy (mechanical clot removal) plus standard medical care or to standard medical care alone. The findings were published in The New England Journal of Medicine in early 2018. The trial was conducted at 26 centers in the United States, Canada, Europe, and Australia, including the Gates Vascular Institute (GVI) under the direction of Elad Levy, MD, MBA, FACS, FAHA, medical director of stroke services at GVI, and an author of the study published by the NEJM. The DAWN trial showed that the patients who received the thrombectomy plus standard medical care had better outcomes in terms of disability and functional independence at 90 days than the patients who received standard medical care alone.

These findings were complemented by those of the DEFUSE 3 trial that involved 38 centers. The trial found that patients who presented with LVOs with a region of brain tissue that was deprived of oxygen (but not yet dead) 6 to 16 hours after stroke symptom onset who received endovascular thrombectomy for ischemic stroke plus standard medical therapy had better functional outcomes than those who received standard medical therapy alone. This trial was stopped early for efficacy.

Due to these findings, the 2018 AHA/ASA Guidelines have new indications for imaging and treatment of stroke patients as shown in Table 1.

The GVI was also one of 15 sites involved in another clinical trial involving AIS treatment. Dr. Adnan Siddiqui was lead investigator and Dr. Elad Levy was the local PI for the COMPASS: a Direct Aspiration First Pass Technique (ADAPT) trial. Most recent stroke trials demonstrating improved patient outcomes with endovascular clot retrieval interventions versus medical therapy used stent retrievers. There has been relatively little investigation of clinical outcomes of patients who were treated with the ADAPT approach, which uses aspiration through a catheter as the first approach to opening up a blocked vessel. The

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Elad Levy, MD, MBA, FACS, FAHA

“For the past decade we have been testing stroke well beyond the 8 hour window. It has been a privilege to be a co-author in both the DAWN and COMPASS studies, proving that we can prevent permanent stroke damage with our state-of-the-art technology.”

- Elad Levy, MD, MBA, FACS, FAHA
### Table 1: Evolution of Stroke Imaging & Treatment Guidelines 2013 to 2018

<table>
<thead>
<tr>
<th><strong>2013 AHA/ASA Guidelines for the Early Management of Patients with Acute Ischemic Stroke</strong></th>
<th><strong>2015 AHA/ASA Focused Update of the 2013 Guidelines for the Early Management of Patients with Acute Ischemic Stroke Regarding Endovascular Treatment</strong></th>
<th><strong>2018 AHA/ASA Guidelines for the Early Management of Patients with Acute Ischemic Stroke</strong></th>
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<tbody>
<tr>
<td><strong>Brain Imaging</strong></td>
<td>Non-contrast CT recommended. CT angiography (CTA) may be considered for selection of patients for endovascular treatment beyond the time window for IV tPA. Evidence of additional benefits beyond CT or CTA such as CT perfusion is unknown.</td>
<td>It is reasonable to proceed with CTA in patients with suspected LVO. In selected patients within 6 to 24 hours of last known normal who have LVO in the anterior circulation, obtaining CTP, DW-MRI, or MRI Perfusion is recommended to aid inpatient selection for mechanical thrombectomy.</td>
</tr>
<tr>
<td><strong>Treatment</strong></td>
<td>The Merci, Penumbra System, Solitaire, &amp; Trevo thrombectomy can be useful in achieving recanalization alone or in combination with tPA. Their ability to improve patient outcomes has not yet been established. Devices should continue to be studied in clinical trials.</td>
<td>Patients should receive endovascular treatment if they meet criteria (ICA or M1 occlusion) within 6 hours of symptom onset. In selected patients with AIS within 6 to 16 hours of last known normal who have LVO in the anterior circulation and meet other DAWN or DEFUSE 3 eligibility criteria, mechanical thrombectomy is recommended (3.7.7). In selected patients with AIS within 6 to 24 hours of last known normal who have LVO in the anterior circulation and meet other DAWN eligibility criteria, mechanical thrombectomy is reasonable (3.7.8).</td>
</tr>
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“*The COMPASS study provides clear evidence that aspiration as a first-line strategy is a valid approach for treating stroke patients with large vessel occlusions.*”

- Adnan Siddiqui, MD, PhD, FAHA, FACS

COMPASS trial was, therefore, aimed at evaluating whether stroke patients with large vessel occlusions LVOs treated with the ADAPT approach within six hours of symptom onset have similar clinical outcomes to those treated with a stent retriever on first approach.

The trial found that the use of ADAPT as first-line mechanical thrombectomy therapy for AIS resulted in similar functional outcomes as those resulting from the treatment with the stent retriever first approach. This finding is significant as the ADAPT approach simply requires the navigation of the aspiration catheter to the clot. The inherent simplicity is complemented by an ability to subsequently use it with a stent retriever if aspiration alone is not sufficient to open up the vessel. The cost saving using the ADAPT approach was significant by not using the stent retriever.

The GVI’s involvement in clinical trials in all of its specialties keeps it on the cutting edge of vascular technologies and ensures that its patients benefit from the best treatments.

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1. *In an endovascular stroke intervention, also called a thrombectomy, a physician threads a catheter through a small puncture in the patient’s leg via the femoral artery to the blockage in the brain. Once there, he/she advances a wire-cage device called a stent retriever through the catheter to the clot where it opens up and adheres to the clot allowing the physician to remove it together with the trapped clot. Suction or aspiration is often used to ensure that pieces of the clot do not break off during removal.*

2. *LVOs are blockages in large blood vessels in the brain including the basilar artery, the carotid terminus and the middle cerebral arteries.*
JI Launches i2R to Accelerate Medical Advances

In March, the Jacobs Institute (JI) launched its i2R, or Idea to Reality Center, a vascular medical device proof-of-concept center, that will bring life-saving interventions to market sooner. The JI also announced its partners that will assist in navigating the regulatory path, engineering medical devices, and providing data analytics expertise. The i2R’s first two projects were revealed, showcasing a medical simulation collaboration project with Moog Inc. and an innovative medical device with Silicon Valley-based company, Spinnaker.

JI’s chief executive officer, Bill Maggio, said, “In keeping with The Future of Medicine book, the JI is launching its i2R, to accelerate future innovations in the treatment of stroke and heart attack, which are devastating the WNY community at rates higher than both the New York State and national average.” Maggio added, “One of our goals is to spin out start-ups from the i2R and encourage them to stay and create jobs right here in Buffalo. There is a reason why Buffalo has raised its visibility as a desirable destination for start-ups. The JI plans to leverage that reputation and the entrepreneurial ecosystem.”

Announcing Corporate Partnerships

JI’s i2R partners NAMSA, Naglreiter, and local company, CUBRC, will assist in navigating the federal regulatory pathway for medical device approval, providing medical device engineering experience, and data analytics expertise critical for product testing, respectively. “The possibilities for vascular device development in the i2R is now limitless. We have the right corporate partners, the right projects, and the right people at the right time. The i2R streamlines and accelerates a challenging process, thereby bringing life-saving vascular devices to reality more easily,” said L. Nelson Hopkins, MD, chief scientific officer.

Announcing First Projects with Moog, Inc. and Spinnaker

JI is expanding into novel, innovative ventures in the medical space. Buffalo-based Moog Inc. will support these collaboration efforts with currently designed medical simulators for dental and eye surgery simulation situated at the JI. They will provide exposure to the broader medical community where brainstorming and feedback on the technologies can be used for enabling new medical products and services. Additionally, the i2R is fortunate to partner with Spinnaker and work with top minds in vascular medical device innovation. “We are eager to collaborate and create life-changing technology with Moog, Inc. and Spinnaker,” said Adnan H. Siddiqui, MD, JI chief medical officer.

The JI is a non-profit organization whose mission is to accelerate the development of next-generation technologies in vascular medicine through collisions of physicians, engineers, entrepreneurs, and industry. The JI’s vision is to improve the treatment of vascular disease in Western New York and the world, while fostering local economic development. The JI can achieve this because collaboration and innovation through partnerships with Kaleida Health, University at Buffalo (UB), and industry, to be a fitting tribute to the work and memory of Lawrence D. Jacobs, MD.

To learn more about the Jacobs Institute i2R, visit idea2Reality.org and watch a whiteboard video that simplifies the i2R innovation process.
Buffalo to Africa: Life-saving Surgical Training

The GVI, in partnership with the Jacobs Institute (JI) and a medical device company, has broadcasted four live electrophysiology cases to 13 African countries, including Angola, Botswana, Cameroon, Congo, Ethiopia, Ghana, Kenya, Nigeria, Rwanda, Senegal, Tanzania, Uganda and Zimbabwe. These are bi-monthly broadcasts to Africa, to train physicians in the latest techniques used to implant vascular medical devices.

The virtual proctorships broadcasts, led by electrophysiologist Chee Kim, MD, FACC, director of electrophysiology at the GVI, were step-by-step demonstrations of the initial insertion of pacemakers, replacements of pacemakers, or upgrades to these devices which control abnormal heart rhythms.

Historically, GVI physicians would travel to countries to provide training opportunities to local medical professionals. With recent advancements, teaching physicians are able to reach a wider audience, creating a more impactful discussion based on the number of international physicians training and participating in the conversation.

"Modern technology is making it possible for medical professionals to collaborate, from all over the world, without ever having to leave their respective countries. This allows us to transform traditional healthcare into a modern healthcare platform, thereby providing new ways to improve patient care,” explained Dr. Kim, when asked about the benefits of the broadcast. Over the course of the two live cases, participants joined the broadcast via mobile device or computer, accompanied with a chat room-like environment. Dr. Kim described, in thorough detail, the correct way to successfully implant a pacemaker—whether for the first time or for a revision or upgrade—while physicians in Africa responded with comments and questions. A medical professional at the GVI fielded the questions during the case while providing present solutions using their clinical knowledge and practice skills.

The GVI and JI broadcasts to Africa are a first-of-their-kind. In total, the GVI and JI have led six other virtual proctorships broadcasts in the United States with plans to do more both nationally and internationally.

Cover Story continued ...

The future of 3D-printed models for presurgical planning at the GVI

Physicians at the GVI in other specialties have also used 3D-printed models for pre-surgical planning. Adnan Siddiqui, MD, PhD, FACS, FAHA, director of neurosurgical stroke service at GVI, has used patient-specific vascular models to plan for complex aneurysm cases and to test the feasibility and effectiveness of particular devices. Vijay Iyer, MD, PhD, director of structural heart intervention for Kaleida Health, used a patient-specific heart model to plan for a ground-breaking complex transcatheter mitral valve replacement. While 2D imaging is sufficient for pre-procedural planning in the majority of procedures, the value of using of 3D-printed models for pre-surgical planning for complex cases is becoming increasingly recognized and its use is poised for further growth at the GVI.
Inside the Gates focuses on the clinical collaborations and cutting-edge treatments at Kaleida Health’s Gates Vascular Institute (GVI).

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This newsletter serves to inform readers about the clinical treatments taking place at the Gates Vascular Institute and does not violate patient privacy.

The GVI’S Telemedicine Program With Olean General Hospital

The last issue of ‘Inside the Gates’ looked at Kaleida Health’s growing telemedicine program including the ability of patients in Olean, a small city about 75 miles southeast of Buffalo, to have remote consultations with GVI cardiothoracic surgeons as part of the work-ups needed prior to transcatheter aortic valve replacement (TAVR) procedures. Vijay Iyer, MD, PhD, FACC, FSCAI, director of the GVI’s structural heart program holds an in-person heart clinic at Olean monthly. Additionally, he is also conducting remote in-patient consultations and rounding with patients at Olean General Hospital as part of the telemedicine program given the shortage of cardiologists there. He says, “Telemedicine is absolutely the wave of the future especially in rural communities where there is not enough business to support clinical sub-specialties. Once small rural hospitals have the appropriate equipment, physicians can do remote consultations from anywhere in the world.”

Using Avizia, a telehealth platform, with facilitation from a nurse/clinician operating the telemedicine cart in Olean, Dr. Iyer is able to listen to patients’ hearts and lungs, remotely review echocardiograms and view patients’ electronic medical records. Using telemedicine, patients are able remain in their own community, but still receive the same quality of care that they would at the GVI. Dr. Iyer has provided about 30 consultations so far and other physicians are being set up to participate in Olean and Lockport. For example, Dr. Bhayana of Great Lakes Cardiovascular is providing general cardiology consults for patients in Medina. As the Kaleida family grows, it will leverage telemedicine to provide care for patients in their own communities, giving them access to specialists they did not have before.